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U.S. Department of Justice
Drug Enforcement Administration

Seminar Report
Controlled Substances Manufacturers and Wholesalers Seminar

San Antonio, Texas

April 7 -9, 1987

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control
Washington, D.C.

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EXECUTIVE SUMMARY

In April of 1987 the United States Drug Enforcement Administration sponsored the first Controlled Substances Manufacturers and Wholesalers Seminar in San Antonio, Texas. Over fifty security and regulatory compliance professionals representing forty-three major pharmaceutical manufacturers and wholesalers were present for three days of presentations and discussions. The focus was upon the problems and techniques of pharmaceutical diversion into the illicit market, and the means to stem this diversion.

Gene R. Haislip, Deputy Assistant Administrator for the DEA's Office of Diversion Control, served as the Seminar Chairman. It was recognized that the abuse of licitly manufactured controlled pharmaceuticals constitutes a formidable public health and safety problem for our society today. Mr. Haislip referred to information contained in the Drug Abuse Warning Network (DAWN) which indicates that approximately 56% of all emergency room drug-related situations result from licitly produced controlled drugs.

The San Antonio Seminar was designed to tap industry security expertise in certain areas of diversion control, and to open communication not only between the industry and DEA but also within the industry. Also explored was the feasibility of DEA acting as a clearinghouse for security intelligence of a specific tactical and immediate nature.

The information that was shared, the good will engendered, and the expertise of the attending individuals all served to make this Seminar a successful start of a joint endeavor to intensify the efforts to combat drug diversion. The Seminar provided a forum for dialogue and a vehicle to encourage a more comprehensive effort.

EDP Security

Dr. Bruce R. Siecker, the Director of Operations and Systems for the National Wholesale Druggists' Association, in his presentation discussed the "Protection and Control of Information Systems in Drug Distribution."

Topics discussed included the meaning of information systems, the need for concern, results of failures to protect information, and threats to information systems and methods of dealing with them. Dr. Siecker's stated that "in order to reap the rich harvest information systems provide, we must learn how to protect and control all aspects. We must recognize the full meaning of information systems, understand the threats, and take appropriate precaution to assure that technology works for us. And, that we can recover from disasters that may slip through our best efforts to protect and control information technology."

Transportation Security

Mr. Herman Lutz, the Director of Regulatory Compliance for McNeil Pharmaceutical, related a number of carrier-related incidents which had resulted in losses. To overcome this problem McNeil developed a "Carrier Security Checklist" for use in inspecting and selecting contract carriers. The evaluation criteria included carrier hiring practices, use of sub-contracted carriers, fencing, security of terminals, shipments held over weekends, verbal and special tracers, personnel and visitor controls, physical controls, high security areas, vehicle and dock controls, and audit controls. Mr. Lutz stated that the checklist has been an excellent tool in evaluating present and potential carriers.

Excessive Order Monitoring Programs

This open session on excessive order monitoring programs was chaired by Ronald Buzzeo. Mr. Buzzeo began by citing the Federal Regulation which requires that registrants design and operate a system to disclose to the registrant suspicious orders of controlled substances. An active discussion followed, centered upon several issues. First, any system must be capable of both detecting individual orders which are suspicious, or orders which become suspicious over a time due to frequency, quantity, or pattern. The NWDA system, for example, provides an excellent lookback, or trend system, but the ability to identify one time suspicious orders should not be overlooked as an element of a program.

Another area of issue was whether DEA would take action against a registrant which reported an order and then shipped it. DEA pointed out that the company is still responsible under their registrations for acting in the public interest. Reporting the order does not in any way relieve the firm from the responsibility for the shipment.

Internal Researcher Controls

Martina R. Perez, Manager of Quality Assurance for E.I. Du Pont de Nemours and Company, opened this presentation by describing two incidents